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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,629 | 10/18/2001 | Kenneth F. Buechler | 071949-1315 | 8727 |

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| EXAMINER |
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ALEXANDER, LYLE

| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 07/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/982,629 | BUECHLER, KENNETH F. |
| | Examiner Lyle A Alexander | Art Unit 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-18 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 74-93, as filed with the 10/8/01 preliminary amendment, have been renumbered under Rule 121 as claims 1-20 respectively.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a capillary method and device having hydrophobic/hydrophilic regions, classified in class 422, subclass 68.1.
- II. Claims 19-21, drawn to method of regulating flow using differing contact angles, classified in class 137, subclass 38+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of being used together because invention I does not require the multiple contact angles to control the fluid flow. Invention I uses hydrophobic/hydrophilic properties to control the flow whereas invention II employs multiple contact angles. Thus the two inventions have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Whittaker on 7/16/03 a provisional election was made with traverse to prosecute the invention of group I, claims 1-17. Affirmation

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of this election must be made by applicant in replying to this Office action. Claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25, 4-16, 1-12, 1-15 of U.S. Patent No. 6,156,270, 6,019,994, 5,885,527 and 5,458,852 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device creating a differential flow rate by arrangement of hydrophobic and hydrophilic zones along a capillary flow path.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kuhn et al.

Kuhn et al. teach a multi-layer test device with a predetermined liquid flow path between a first and second layer, reaction sites(15) containing reagent and a vent(19). The first and second layers have differential wicking characteristics created by use of a hydrophobic material in one layer and hydrophilic in the other (see claim 4). The taught flow path has been read on the claimed capillary channel and the first/second layer on the claimed first/second capillary regions. The reaction sites(15) containing reagents in the dry state that are activated by the aqueous sample and have been read on the claimed dried reagents.

Claim Rejections - 35 USC § 112

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is duplicate of claim 5 and should be deleted.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Mr. Whittaker on 7/16/03.

Applicant requested claims 74-93 found in the 10/18/02 preliminary amendment replace claims 74-93 as originally filed.

Additionally, Applicant should note claims 74-93 have been renumbered under Rule 121 as 1-21 respectively.

Finally, the non-USP reference cited in the 2/14/02 IDS have not been considered because copies of these documents were not readily available. Applicant has noted all of these references were cited in an earlier application. The Office will order the application and consider the references at that time. Alternatively Applicant could also supply copies of the non-USP references for consideration in the response to this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Lyle A Alexander
Primary Examiner
Art Unit 1743

